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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,594	07/01/2003	Sheng-Ping L. Hwang	ACAD/0002	3435

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EXAMINER
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JOIKE, MICHELE K

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/612,594	<b>Applicant(s)</b> HWANG ET AL.	
	<b>Examiner</b> Michele K. Joike, Ph.D.	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 20-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on June 16, 2006 is acknowledged. The traversal is on the ground(s) that a reasonable number of species are claimed. Only five nucleotide sequence species are claimed and all of them are from the zebrafish BMP4 gene. This is not found persuasive because the nucleic acid sequences are non-overlapping. Each sequence will produce a different product that is structurally different from the other.

The requirement is still deemed proper and is therefore made FINAL.

### ***Specification***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Figure 2 contains an amino acid sequence that needs a sequence identifier.

### ***Claim Objections***

Claims 1, 20 and 22 are objected to because of the following informalities: The claims contain nonelected sequences. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-5 and 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 20-22 are vague and indefinite because they recite "derivatives and fragments thereof" and it is unclear what derivatives of SEQ ID NO:1 would retain BMP4 activity. Claims 21 and 22 also recite the language "derived from SEQ ID NO: 1". The metes and bounds of the claimed subject matter are unclear because it is unclear how closely related to the original starting material (SEQ ID NO: 1) the derivatives are. The skilled artisan would be unable to determine which molecules are encompassed by the "derivative" language and which are not.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 20-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated DNA molecule comprising SEQ ID NO: 1 and derivatives thereof. The claims read on a broad genus of possible derivative of the isolated DNA molecule.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicants were in possession of the claimed invention. In the instant case, the specification does not sufficiently describe a representative number of mutations or alterations (derivatives) to SEQ ID NO: 1 that would allow it to still function as a BMP4 protein.

The specification does not teach how to mutate or alter the sequence in order to maintain the function of the gene. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification does not disclose any derivatives of SEQ ID NO: 1.

The state of the art at the time of filing does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the art that allows one to envision a representative number of derivatives by disclosing structural or functional features of the possible derivatives so that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot

consult the art at the time of filing to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the state of the art at the time of filing teaches a structure-function relationship for a representative number of derivatives. As a result, the skilled artisan would not be able to envision the claimed invention. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 20 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank accession number AY156927.

Claims 1, 20 and 22 claim an isolated DNA molecule encoding the zebrafish BMP4 gene comprising a nucleic acid sequence of SEQ ID NO: 1. Genbank accession number AY156927 is the BMP4 gene (SEQ ID NO: 1) submitted September 30, 2002 by two of the three current inventors. Therefore, Genbank accession number AY156927 anticipates claims 1, 20 and 22.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,071,518.

Applicants teach an isolated DNA molecule encoding the zebrafish BMP4 gene comprising a nucleotide sequence of SEQ ID NO: 1, and derivatives and fragments. They also teach an expression vector comprising a portion of the DNA molecule, the expression vector with a reporter, and the cell containing the isolated DNA molecule. The reporter can be  $\beta$ -galactosidase. Fragment is defined as a DNA molecule having at least 15 nucleotides.

US 6,071,518 (specifically column 3, lines 39-41, column 10, column 16, 20 and example 11) teach a GP900 glycoprotein (SEQ ID NO: 2), an expression vector containing the GP900 gene (Bluescript and pFusTrx), and verification of the GP900 reading frame by expression of two clones, S34 and Ag 4 as  $\beta$ -galactosidase fusion proteins. Vectors were transformed into prokaryotic and eukaryotic cells. Since Applicants claim an isolated nucleic acid comprising a nucleotide sequence of SEQ ID NO: 1 and fragment thereof, any fragment (15 or more consecutive bases) reads on the invention. Therefore, the 19 nucleotide bases of the GP900 gene, the GP900 gene in an expression vector and the vector in a variety of cell types reads on a fragment of a nucleotide sequence of SEQ ID NO: 1, as well as an expression vector containing a portion of SEQ ID NO: 1 and a cell containing the isolated DNA molecule of SEQ ID NO: 1. As such, US 6,071,518 anticipates every aspect of the claimed invention.

***Allowable Subject Matter***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CELINE QIAN, PH.D.  
PRIMARY EXAMINER



Michele K Joike, Ph.D.  
Examiner  
Art Unit 1636